Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

30th March 2023

FOI 23/222

Dear [redacted]

Thank you for your FOI request dated 28th March 2023.

We can confirm that we do not hold the information that you have requested. As the original marketing authorisation application for "**Procyclidine Hydrochloride 5 mg Tablets, Kemadrin Tablets 5mg of Aspen Pharma Trading Limited, Ireland**" was made prior to the 2012 amendment in pharmacovigilance legislation, which requires an RMP for all new applications, the MHRA does not hold an RMP for this product.

If you have a query about the information provided, please reply to this email.

Please remember to quote the reference number above in any future communications.

Yours sincerely

FOI Team,

Safety and Surveillance
Medicines and Healthcare products Regulatory Agency

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Water Lane
Wilmslow
Cheshire
SK9 5AF